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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,305	03/09/2007	Timothy Hla	UCT0051US2	9420

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
03/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,305	HLA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9 and 22* is/are rejected.

7)☒ Claim(s) *7-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's After-Final Amendment filed February 09, 2010 has been received and entered into present application. Claims 2-6 and 10-21 were canceled and claim 22 was added by applicant. Thus claims 1, 7-9 and 22 are pending.

Applicant's amendments to the claims overcame the rejections of record, however new rejections are applicable and detailed below. Because these new rejections were not necessitated by amendment, the **finality of the last office action is WITHDRAWN.**

Applicants' arguments, filed February 09, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 7-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In claims 7 and 8 applicant claims the method of claim 1 wherein the receptor of claim 1 is a S1P1 or S1P2 receptor (claim 7) or where the agonist induces adherens

junction assembly (claim 8). These are merely properties of the one SP1 receptor agonist claimed in claim 1 and do not further limit the claim as the method of claim 1 would inherently have these effects.

Priority

Applicant has indicated that the instant application is a 371 of PCT/US04/19420 with a filing date of June 18, 2004 and claims priority to the provisional application 60/482,234 which has a filing date of June 24, 2003. The provisional application 60/482,234 lacks written description for the instant claims. The instant claims are drawn to a method of treating "an individual", and the provisional application only encompasses treatment of mammals, and not to any individual which can encompass non-mammals such as amphibians and reptiles. Thus the instant claims do not have support in the provisional application and thus priority is not granted to 60/482,234. **The current effective filing date of this application is June 18, 2004.**

Election of species

Because treatment of adult (acute) respiratory distress syndrome is free of the art and to expedite the examination of this application, the search was expanded beyond that specific vascular permeability disorder to the other disorders listed in claim 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 9 and 22, applicant claims "adult (acute) respiratory distress syndrome". It is unclear what the parenthesis mean in the term, is this a limitation or would adult respiratory distress syndrome also be encompassed by the claims? It does not appear to be the common way to refer to that disease, which is usually merely referred to as acute respiratory distress syndrome (ARDS). One of skill in the art would not be able to determine what applicant meant by the parenthesis in claims 9 and 22.

Additionally, in claim 22, applicant claims a method of treating an individual in need of treatment for adult (acute) respiratory distress syndrome, comprising administering to a the individual in need of treatment for a vascular permeability disorder. It is unclear what the patient population is as applicant is claiming treatment of a specific disorder and referring to "the patient" which refers back to the patient with ARDS but then states the individual is in need of treatment for a vascular permeability disease which is a much broader patient population. Thus it is not clear to one of ordinary skill in the art at the time of the invention who the patient population of claim 22 is.

For these reasons claims 9 and 22 fail to particularly point out and claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 7-9, and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Sanchez et al. (Phosphorylation and action of the immunomodulator FTY720 inhibits vascular endothelial cell growth factor-induced vascular permeability, cited on applicant's IDS).

As discussed above, the current effective filing date for the instant claims is June 18, 2004. As such, the art of Sanchez et al. applies as 102(a) art. Some of the inventors are the same, however they are not identical so Sanchez et al. currently applies as prior art.

In claim 1, applicant claims a method of treating an individual in need of treatment for a vascular permeability disorder by administering the SP1 receptor agonist FTY720. Sanchez et al. teaches that FTY720 is an immunosuppressive agent and that it potently blocked VEGF-induced vascular permeability in vivo. They further suggest that it can be used to regulate vascular permeability (abstract). Thus they teach administering FTY720 to individuals (mice) in need of treatment for a vascular permeability disorder and Sanchez et al. anticipates claim 1.

In claims 7-8, applicant merely claims properties and results of the method of claim 1. Since Sanchez et al. anticipates claim 1, it would have the same effect and thus anticipates clams 7 and 8 as well.

In claim 9, applicant claims specific vascular permeability disorders. Sanchez et al. specifically teaches using FTY720 for treatment of sepsis (abstract) and thus anticipates claim 9 as well.

In claim 22, applicant claims a method of treating adult (acute) respiratory distress syndrome, by administering to a patient in need of treatment of a vascular permeability disease. As discussed above, Sanchez et al. teaches treatment of vascular permeability and sepsis specifically and thus teaches the same patient population and the method of Sanchez et al. would inherently result in the same treatment of adult (acute) respiratory distress syndrome and claim 22 is also anticipated by Sanchez et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7-9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty et al. (US 2004/0058894 A1).

In claim 1, applicant claims a method of treating an individual in need of treatment for a vascular permeability disorder by administering the SP1 receptor agonist FTY720. Doherty et al. teaches using treating immunoregulatory abnormalities with SP1 receptor agonists (abstract). They specifically teach FTY720 as an immunosuppressive agent that is used to treat autoimmune disorders and is a SP1 receptor agonist (page 1, [0007]). They further teach vasculitis, as well as sepsis, and atherosclerosis as immunoregulatory disorders to be treated with SP1 receptor agonists (page 4, [0051]). Vasculitis is an autoimmune disease, and it would have been obvious to one of ordinary skill in the art that autoimmune vasculitis is included in the teachings of Doherty et al. as they teach autoimmune diseases and vasculitis specifically. Doherty et al. does teach a large list of diseases, however it would be obvious to one of ordinary skill in the art at the time of the invention that immunosuppressant's are known to treat autoimmune diseases in general, and the list of diseases in Doherty et al. is a standard list of autoimmune type of diseases and it would have been obvious that FTY720 could be

used to treat any of those diseases with a reasonable expectation of success as they autoimmune diseases. Thus claim 1 is unpatentable of Doherty et al.

In claims 7-8, applicant claims properties and results of the method of claim 1. Since Doherty et al. teaches the same drug to the same patients it would necessarily have the same action on the same receptors and have the same results. Thus claims 7 and 8 are also unpatentable over Doherty et al. for the reasons discussed above.

In claim 9, applicant claims that the vascular permeability disease in claim 1 includes atherosclerosis, autoimmune vasculitis, and sepsis. Each of these is taught by Doherty et al. (page 4, [0051]) and thus claim 9 is also unpatentable over Doherty et al.

In claim 22, applicant claims a method of treating adult (acute) respiratory distress syndrome, by administering to a patient in need of treatment of a vascular permeability disease. As discussed above, it is unclear what the patient population is, but the broadest reasonable interpretation includes patients in need of treatment for a vascular permeability disease, such as vasculitis or sepsis. Thus the method of Doherty et al. would necessarily result in the treatment of acute respiratory distress syndrome as it is the same drug being administered to the same patient population. Thus claim 22 is also unpatentable over Doherty et al. for the reasons discussed above.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614